

Pharma Enhancements

MDS User Group 2017



Agenda

- > HDA EDI 856/E-Pedigree Track and Trace
- > Serialization and Traceability
- > Suspicious Order Monitoring System (Excessive Product Usage)
- CSOS Options
- > Pedigree T3 Document
- > Track and Trace Options
- > ARCOS and Reporting Updates



- Speed Eliminates the need to manually update the newly created pedigree
- Accuracy Information is coming directly from your vendor/manufacturer
- > Streamlined Process Saves your company time and effort



How would you rate the operational efficiency of your track and trace system?

It is fully optimised 9.3%

It is very strong, with some fine tuning needed 24.1%

he system is functional but efficiency needs significant improvements 20.4%

The system is functional but process is inefficient in areas 13.0%

Operational efficiency is a big focus for us at the moment 16.7%

Other (please specify) 16.7%

Too early to say for the above function

Each implementation must be customized to fit the specific needs

No comparison available

Meets Reg expectations

*Pharmaceutical Serialization and Traceability 2017 Market Trend Repor



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Meets Rag expectations

The results show that less than 10% of businesses believe they are full optimized.

Pharmaceutical Serialization and Traceability 2017 Market Trend Report

How would you rate the operational efficiency of your track and trace system?

It is fully optimised 9.39

It is very strong, with some fine tuning needed 24.1%

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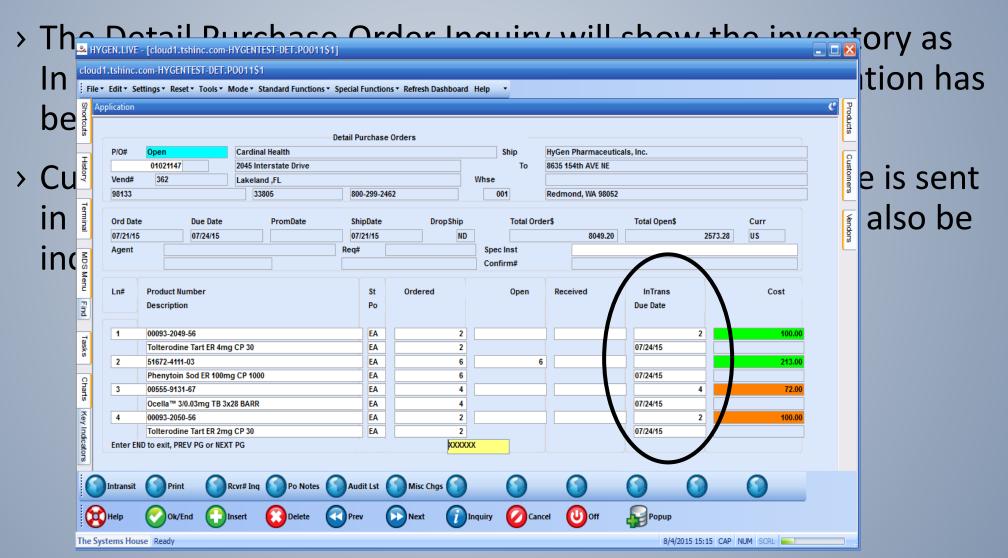
TSH is always changing to update the needs of our customers. We incorporate any and all requirements as part of our regular software updates. The goal is to have all of you in the top 10%.

Pharmaceutical Serialization and Traceability 2017 Market Trend Report



- The Detail Purchase Order Inquiry will show the inventory as In Transit and the Expected Deliver Date when information has been received
- Currently, the lot information, including expiration date is sent in the EDI record. In the future, the serial number will also be included







At PO Receiving time, you will select the Intransit record that was created

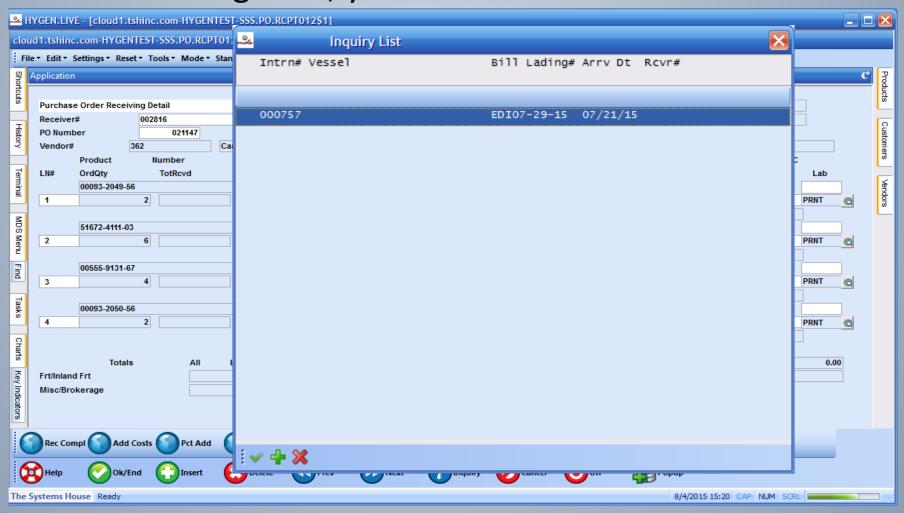


> At PO Receiving time, you will select the Intransit record that

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> At PO Receiving time, you will select the Intransit record that





- > The Pending Pedigree Selection screen will show for any incoming Pedigree items
- > If desired, you can see detailed Pedigree information by clicking on the Pedigree Detail button



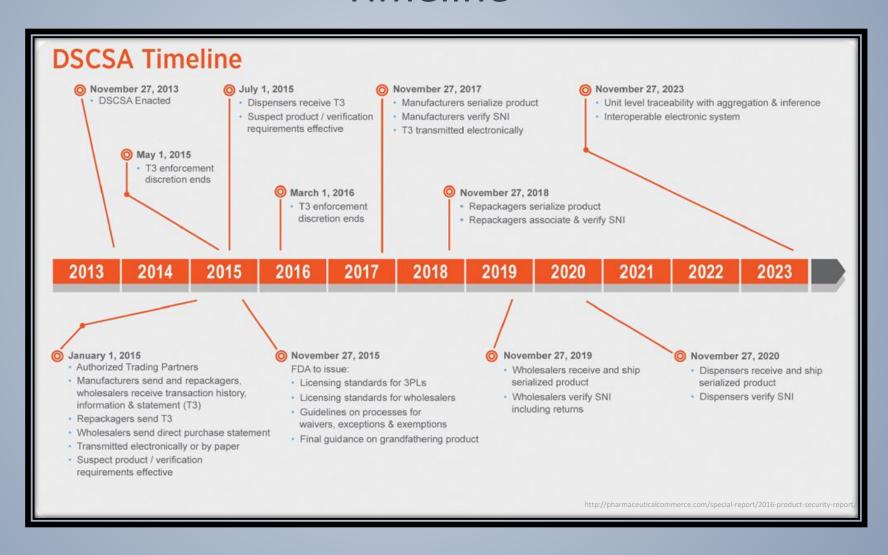
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Federal Drug Supply Chain Security Act (DSCSA) Timeline

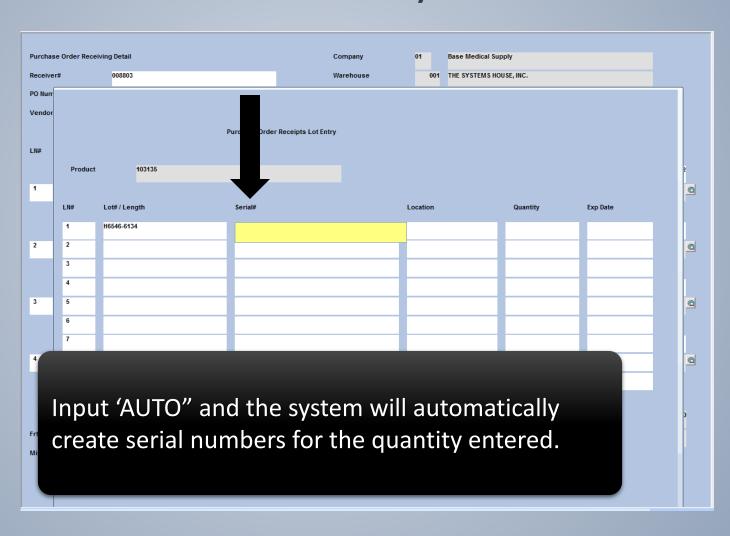




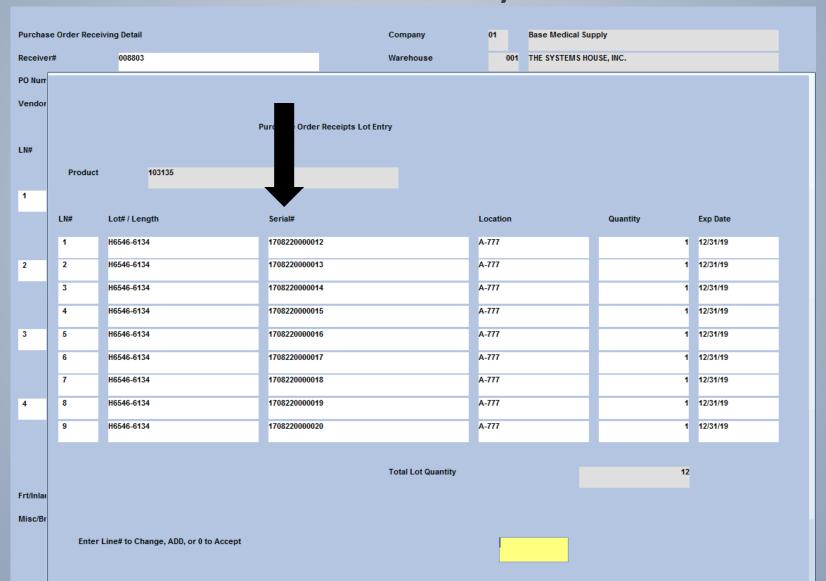
> Supply chain visibility is enabled through serialization with tracking being applied on single units.













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Page 1 of 1 Lot Tracking Report 08/22/2017 13:51:32 DATE TNX LOT NO QUANTITY **LOT SERIAL NO CUST NO** WHSE **PRODUCT** INVOICE / REL NO 001 103135 A02347 Phentoin Sodium ER 100mg 1000ct 8/22/2017 H6546-6134 1708220000012 RACHEL 01A35668001 INV 001 103135 A02347 Phentoin Sodium ER 100mg 1000ct 8/22/2017 INV H6546-6134 1708220000014 RACHEL 01A35668001 103135 A02347 001 Phentoin Sodium ER 100mg 1000ct 8/22/2017 INV H6546-6134 1708220000013 RACHEL 01A35668001



- > Utilizing GS1 Standards there are 3 components:
 - Identify Using globally unique identification keys
 - GLN Global Location Number. Your company and warehouses will have a unique GLN number. Also, all of your customers and their shipto's will have GLN numbers assigned by GS1.
 - > GTIN Global Trade Identification Number. Each item will have a unique GTIN for each saleable unit of measure.
 - SSCC Serial Shipping Container Code. Serial shipping container is used to identify items packaged together for transport.
 - Capture by utilizing barcode scanning
 - > GS1 DataMatrix barcode is read by camera-based bar code scanners.
 - Contains: GTIN, Expiration Date, Lot Number and Serial Number of the item
 - > GS1-128 line bar code. Easily read by a handheld scanner.



> Utilizing GS1 Standards there are 3 components:

Identify – Using globally unique identification keys

> GLN-Example: Use of GS1 Standards for the identification of products using a GS1 DataMatrix unique numb

> GTIN for each

> SSCC

GTIN: (01) 07046261398572

Expiry: (17) 130331 Batch / lot: (10) TEST5632 (21) 19067811811

warehouses will have a hd their shipto's will have GLN

tem will have a unique GTIN

ping container is used to

- Capture by utilizing barcode scanning
 - > GS1 DataMatrix barcode is read by camera-based bar code scanners.
 - Contains: GTIN, Expiration Date, Lot Number and Serial Number of the item
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ping container is used to

(01) 10222222333334(17) 091231(10) A1345B(21) 1234

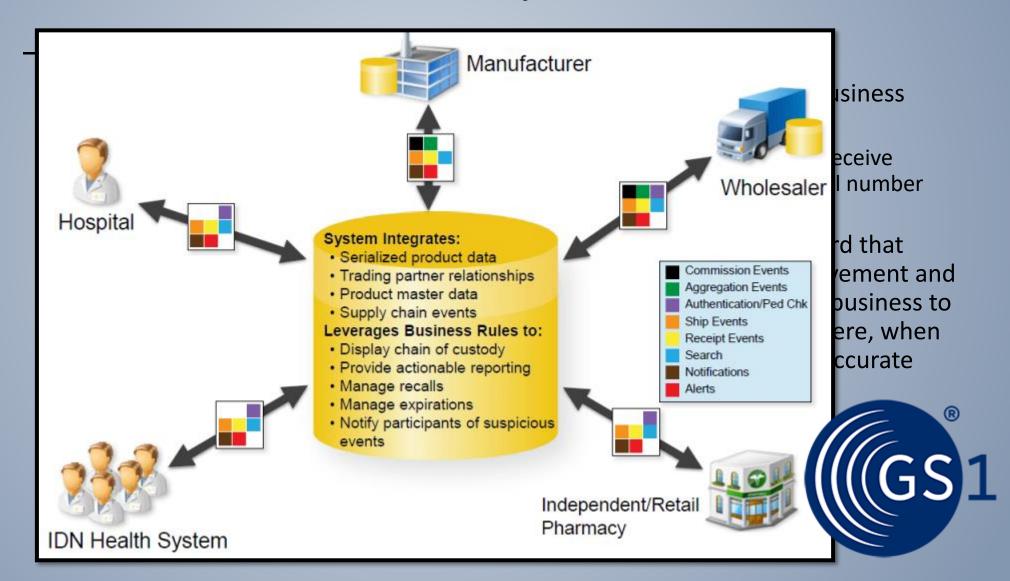
contains: Grin, Expiration Date, Lot Number and Serial Number of the Item

> GS1-128 line bar code. Easily read by a handheld scanner.



- Share Exchange of business-critical information
 - > EDI (Electronic Data Interchange) Is the electronic interchange of business information using a standardized format.
 - Many of our customers are utilizing this option. Currently we send and receive product information that includes the lot number. In the future the serial number will also be transmitted.
 - EPCIS Electronic Product Code Information Services is a GS1 standard that enables trading partners to share information about the physical movement and status of products as they travel throughout the supply chain – from business to business and ultimately to consumers. It helps answer the "what, where, when and why" questions to meet consumer and regulatory demands for accurate and detailed product information.







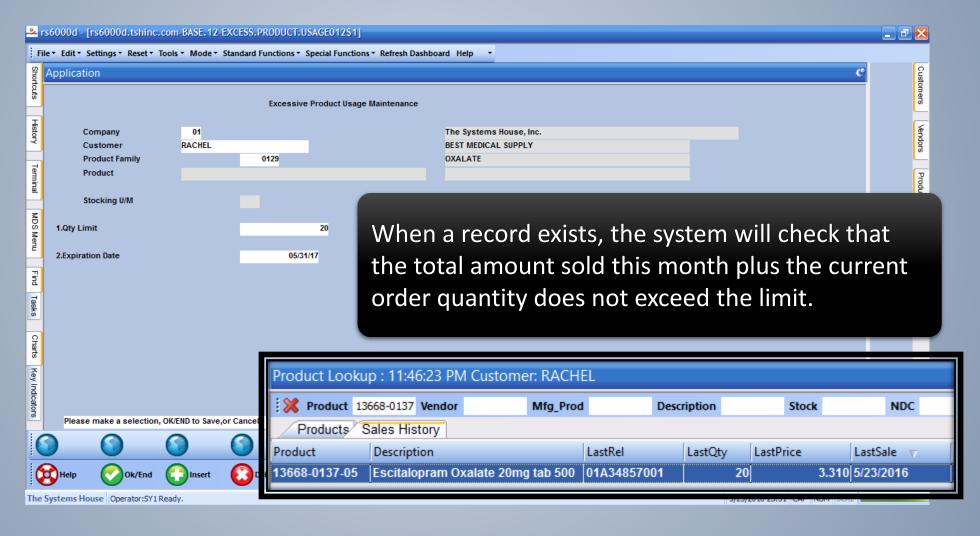
Suspicious Order Monitoring System

(Excessive Product Usage)

- > Typically used to monitor and control the quantity of controlled substances sold to a customer
- Can also be used for customer allocations to limit the amount of stock customer's can order. By doing this, you will be able to fulfill multiple customer orders, instead of one customer wiping out your stock
- > This is constantly being updated, as we now have expanded the options for its usage:
 - By specific customer
 - By specific product family
 - By specific product

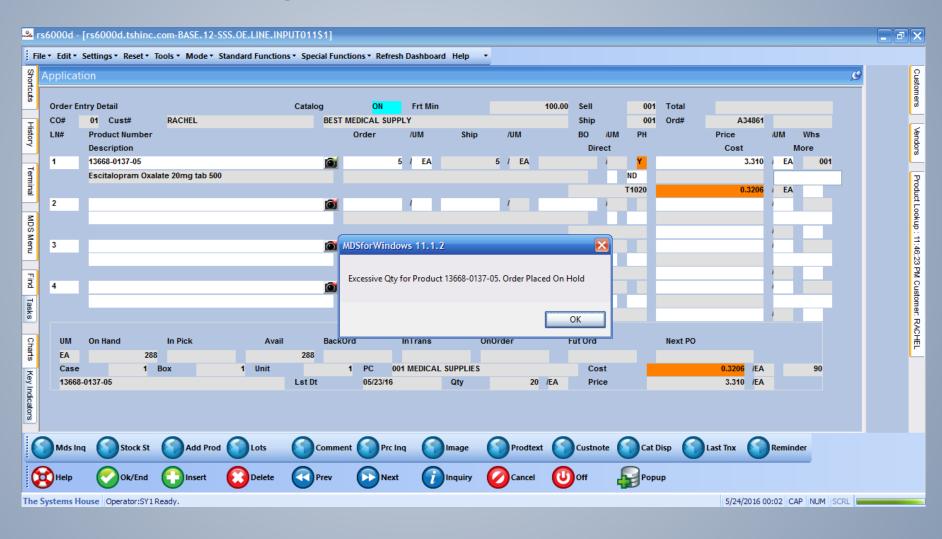


Suspicious Order Monitoring System (Excessive Product Usage)





Suspicious Order Monitoring System (Excessive Product Usage)

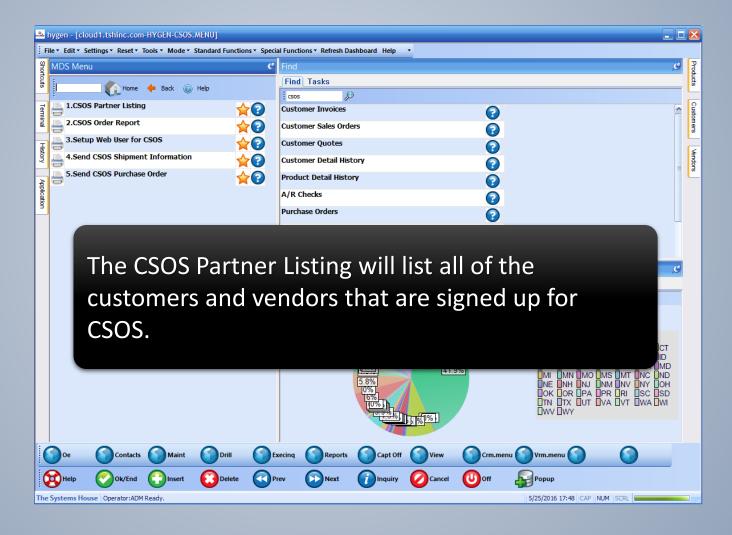




- For those selling controlled drugs:
 - Utilizing CSOS Integrated system with Legisym and their product Express222
 - Various Setup Options:
 - > Integrated with RemoteNet
 - > EDI
 - Order Entry
 - MDS optional module









SORT CSOS.PARTNER DEA.NO PARTNERID USERNAME ID-SUPP LPTR 05:47:56pm 25 May 2016 PAGE 1
DEA#.... Partner ID Username.....

FM2503692 102878 102871

1 records listed.



SORT CSOS.XREF CSOS.TRACKNO FILEKEY FILENAME E222ORDERID SIGNED.DATE SENT.DATE ID-SUPP LPTR 05:54:07pm 25 May 2016 PAGE 1 Tracking Number File Key. File CSOS Order Id Date.... Date Shipped

16XN00001 142091 WEB.ORDER 765174

16XN00002 142168 WEB.ORDER 766237 03/04/16

2 records listed.

The CSOS Order Report will show all incoming orders with their tracking numbers, date placed and shipped.



The Pedigree (T3)

- > The three sections of the Pedigree:
 - Transaction Information (TI)
 - Transaction History (TH)
 - Transaction Statement (TS)



The Pedigree (T3)

Base Medical Supply

Drug Supply Chain Security Act Document Doc#0000001250

(TI) Transaction Information

Drug Name, Strength, Dosage Form, Container Size:

Phentoin Sodium ER 100mg 1000ct,

NDC: 54221-4511-02

Lot Number	Quantity	Unique Serial #
H6546-6134	1	1708220000023

Reference Number:

Document Type:

Invoice

01A02351

08/28/17 Reference Date:

(TH) Transaction History

Manufacturer's Name: Mckesson United

Manufacturer's information: 1100 Corporate Way NEW YORK, NY 12344 mck@mckesson.com 212-555-1212

SOLD TO:

Name: Mckesson United Address: 1100 Corporate Way

NEW YORK NY 12344

5645441 Date Purchased & Ref: 08/11/17

SHIPPED TO:

Mckesson United Address: 1100 Corporate Way **NEW YORK NY 12344**

Date Received & Ref:

SOLD TO:

Base Medical Supply Address: 1033 US HIGHWAY 46 East

CLIFTON NJ 07013

Date Purchased & Ref: 08/22/17 PO#01136151 SHIPPED TO:

Base Medical Supply Address: 1033 US HIGHWAY 46 East

CLIFTON NJ 07013

Date Received & Ref: 08/22/17

RC#008803

SOLD TO:

BEST MEDICAL SUPPLY

Address: 1033 RT 46

HOWELL HI 07731

Date Purchased & Ref: 08/28/17

SHIPPED TO:

BEST MEDICAL SUPPLY

Address: 1033 RT 46

HOWELL HI 07731

Date Received & Ref: 08/28/17

SOLD TO: Name:

SHIPPED TO: Name:

- > TI Transaction Information -The description of the drug
- > TH Transaction History Tracks each step of the supply chain, back to the manufacturer
- > TS Transaction Statement -Provides the legal statement of compliance



The Pedigree (T3)

Base Medical Supply

Drug Supply Chain Security Act Document Doc#0000001250

(TI) Transaction Information

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Lot Number	Quantity	Unique Serial #
H6546-6134	1	1708220000023

Reference Number:

Document Type: Invoice

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08/28/17

01A02351

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SOLD TO:

SOL Nam

Addr

SOL

Addr

Date

Name: Mckesson United Address: 1100 Corporate Way

NEW YORK NY 12344

Date Purchased & Ref: 08/11/17 5645441

SHIPPED TO:

Name: Mckesson United
Address: 1100 Corporate Way
NEW YORK NY 12344

Date Received & Ref :

- TI Transaction Information The description of the drug
- TH Transaction History Tracks each step of the supply chain, back to the manufacturer
- TS Transaction Statement Provides the legal statement of compliance

(TS) Transaction Statement: This Company complied with each applicable subsection of FDCA Sec. 581 (27) (A) - (G)

- (A) is authorized as required under the Drug Supply Chain Security Act;
- (B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;
- (C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;
- (D) did not knowingly ship a suspect or illegitimate product;
- (E) had systems and processes in place to comply with verification requirements under section 582;
- (F) did not knowingly provide false transaction information; and
- (G) did not knowingly alter the transaction history.



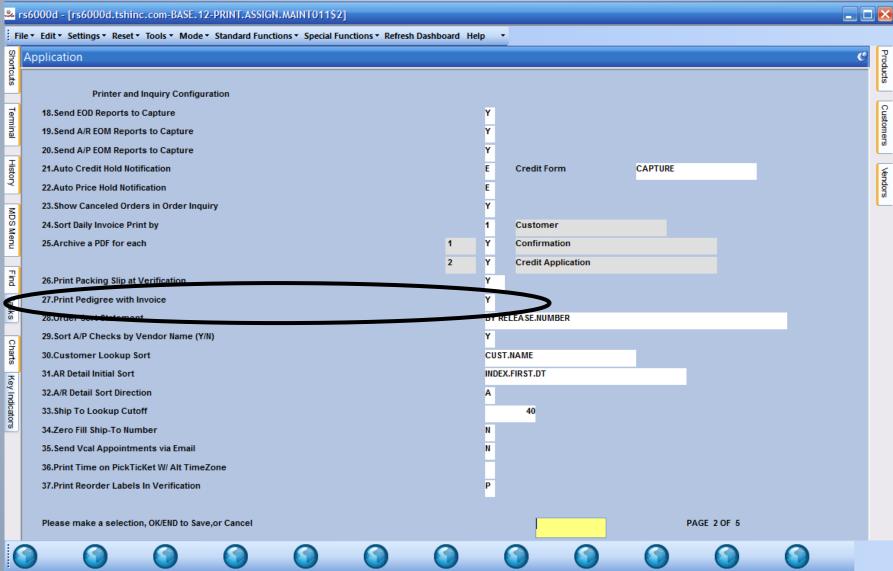
Track and Trace Options

- > Options on when to print the Pedigree
- > Option to show credits/returns on the printed Pedigree
- > Optional Repackaging module

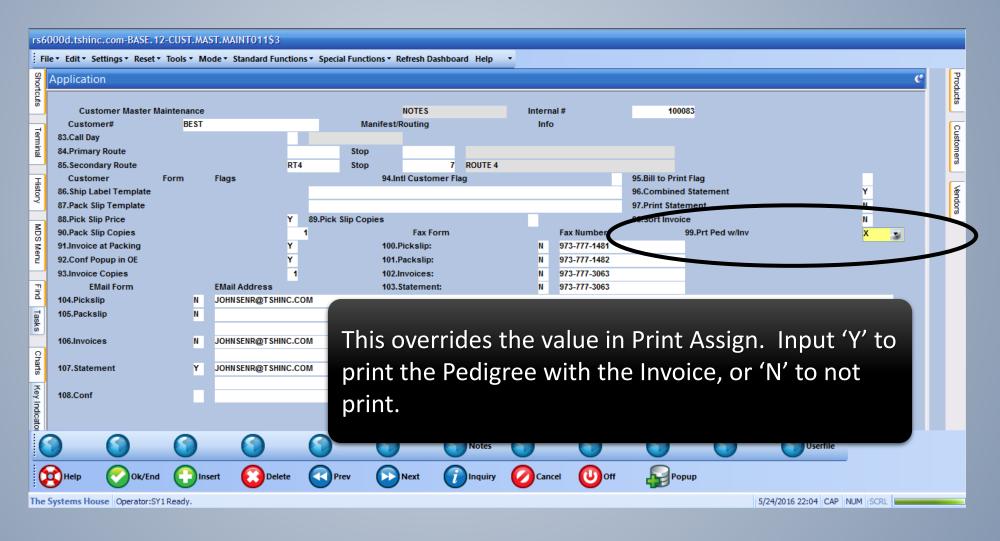


> When to print the pedigree









Drug Supply Chain Security Act Document Doc# 0000001250

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Drug Name, Strength, Dosage Form, Container Size: Phentoin Sodium ER 100mg 1000ct,

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Lot Number	Quantity	Unique Serial #
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Wallulacturer 3 Illionnation. 1100 Corporate Way NEW 10	TRANSPORTER
SOLD TO: Name: Mckesson United Address: 1100 Corporate Way NEW YORK NY 12344 Date Purchased & Ref : 08/11/17 5645441	SHIPPED TO: Name: Mckesson United Address: 1100 Corporate Way NEW YORK NY 12344 Date Received & Ref:
SOLD TO: Name: Base Medical Supply Address: 1033 US HIGHWAY 46 East CLIFTON NJ 07013 Date Purchased & Ref: 08/22/17 PO#01136151	SHIPPED TO: Name: Base Medical Supply Address: 1033 US HIGHWAY 46 East CLIFTON NJ 07013 Date Received & Ref: 08/22/17 RC#008803
SOLD TO: Name: BEST MEDICAL SUPPLY Address: 1033 RT 46 HOWELL HI 07731 Date Purchased & Ref: 08/28/17	SHIPPED TO: Name: BEST MEDICAL SUPPLY Address: 1033 RT 46 HOWELL HI 07731 Date Received & Ref: 08/28/17
SOLD TO: Name: Address: Date Purchased & Ref :	SHIPPED TO: Name: Address: Date Received & Ref :
SOLD TO: Name: Address:	SHIPPED TO: Name: Address:
Date Purchased & Ref :	Date Received & Ref :

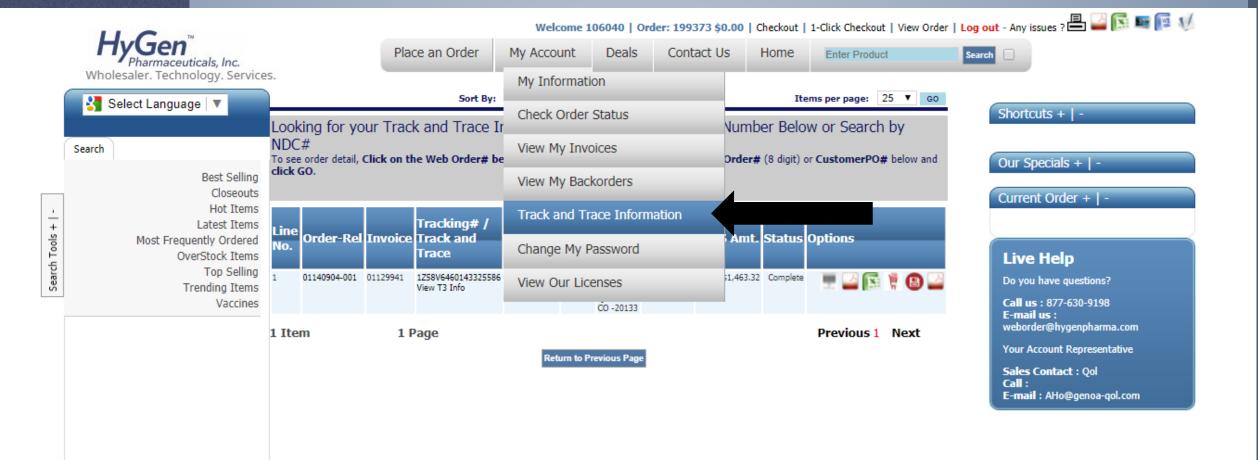
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Trace and Trace Options The Pedigree (T3)

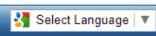
For those using Remotenet, your customers can view and print their Pedigree's directly from the website.

Page: 1 of 1 pages





Best Selling



Search

Closeouts
Hot Items
Latest Items
Most Frequently Ordered
OverStock Items
Top Selling
Trending Items
Vaccines

Looking for y NDC# To see order detail click GO.

5	Line No.	Order-R
1	1	01140904-0

1 Item

HyGen

HyGen Pharmaceuticals, Inc.

Doc# 10000050031

Pharmaceuticals, Inc. Drug Supply Chain Security Act Document

(TI) Transaction Information

Drug Name, Strength, Dosage Form, Container Size:
Afluria® QIV 2017-18 5ml MDV 10 ,
Dose SEQI (Influenza Vaccine)
NDC: 33332-0417-10

Lot Number Quantity Unique Serial # Reference Date: 09/07/17

O1044611A 8

(TH) Transaction History

Manufacturer's Name: Seqirus, Inc Manufacturer's information: Cambridge, MA

SOLD TO: Name: Seqirus, Inc Address:	SHIPPED TO: Name: Seqirus, Inc Address:	
Cambridge MA Date Purchased & Ref :	Cambridge MA Date Received & Ref :	
SOLD TO:	SHIPPED TO:	

SOLD TO	SOLD TO:			SHIPPED TO:		
Name:	HyGen Pharma	aceuticals, Inc.		Name:	HyGen Pharmaceuticals, Inc	
Address:	Address: 8635 154th AVE NE			Address: 8635 154th AVE NE		
\$50.50 VSC 2029	Redmond WA	98052		6.888,000,00	Redmond WA 98052	
Date Pur	chased & Ref	08/16/17	PO#01025223	Date Rec	eived & Ref · 09/05/17	

SOLD TO	D:		SHIPPE	D TO:		
Name:	Genoa-QoL Phcy CO -20133		Name:	GENOA-QOI	PHCY CO -	20133
Address:	18300 Cascade AVE S		Address:	8745 COUNT	TY ROAD 9 S	OUTH
Maria	Tukwila WA 98188			ALAMOSA C	O 81101	
Date Pur	chased & Ref : 09/07/17	01140904001	Date Rec	eived & Ref	09/07/17	01140904001

Date Purchased & Ref : 09/07/17	01140904001	Date Received & Ref: 09/07/17	01140904001
SOLD TO:		SHIPPED TO:	
Name:		Name:	
Address:		Address:	
Date Purchased & Ref		Date Received & Ref :	

Date Furchased & Rei .	Date Received & Rei :	
SOLD TO:	SHIPPED TO:	
Name:	Name:	
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Date Purchased & Ref :	Date Received & Ref :	

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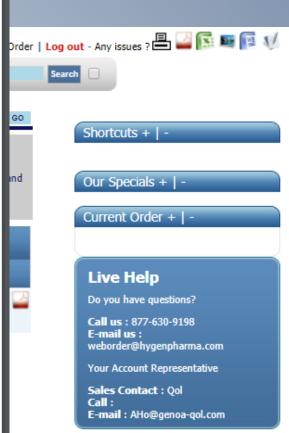
This wholesale distributor purchased the specific unit of the prescription drug directly from the manufacturer.

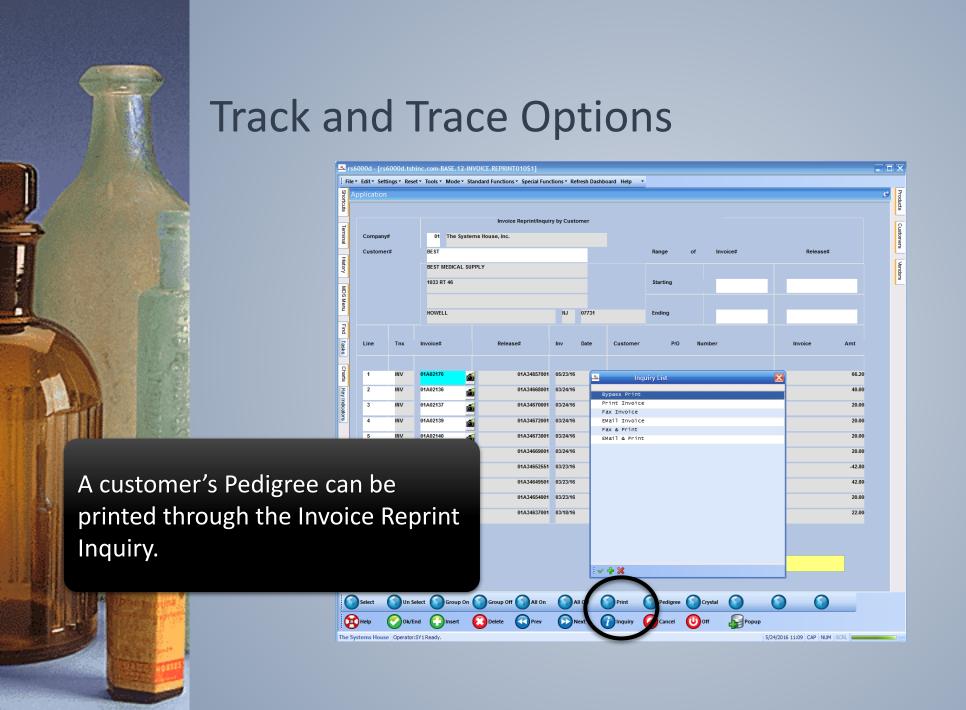
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pages.



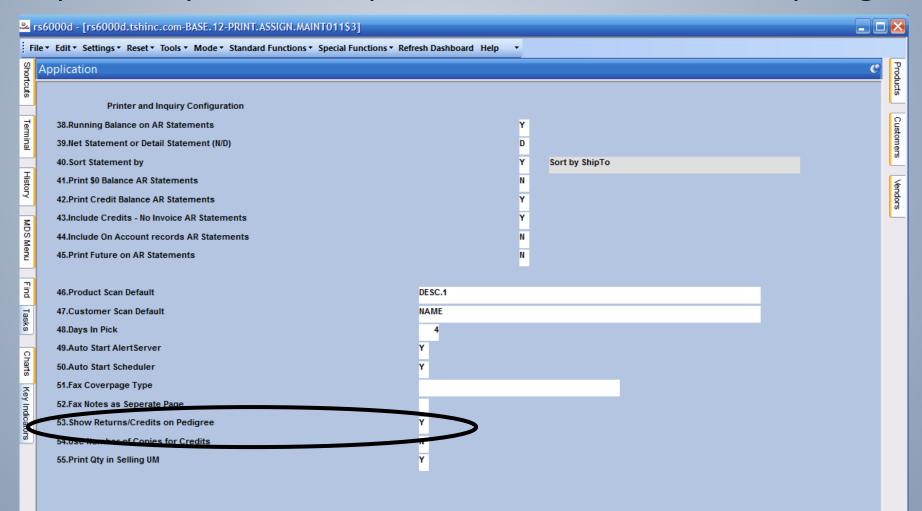




> Option to print or not print credits/returns on the pedigree



> Option to print or not print credits/returns on the pedigree





directly through MDS.

Track and Trace Options

US MEDSOURCE	US MedSource, LLC Drug Supply Chain Security A	(Repackager's Name) Act Document Doc# 00000001366
(TI) Transaction Information: Des Drug Name, Strength, Dosage Form, Conta Manufacturer / Repackager Name on Conta NDC on Container: Lot Number Quantity 000026 1	iner Size: LIDOCAINE HCL 2% MDV INJECTION, 1/VL	S-543-4414
(TI) Transaction information: Description of Drug Received	(TH) Transaction History Manufacturer's Name: HOSPIRA WORLDWIDE INC Manufacturer's information: 1635 STONE RIDGE DRIVE S	STONE MOUNTAIN, GA 30083 877-946-7747
Product Information: USE HOS-0427702 Lotz: 41-407-DK-01 Supplier: GENERAL INJECTIBLES & VAC 80 SUMMIT VIEW LANE BASTIAN, VA 24314	SOLD TO: Name: US MEDSOURCE SARASOTA Address: 2280 TRAILMATE DRIVE SARASOTA FL 34243 Date Purchased & Ref: 0608/15 LOT 000026	SHIPPED TO: Name: US MEDSOURCE SARASOTA Address: 2280 TRAILMATE DRIVE SARASOTA FL 34243 Date Received & Ref : 06/08/15 DOC 01001014001
Date Purchased/Ref#: DOC 12335329 DOC 123 Date Received/Ref#: 05/06/15 DOC 12336 NDC#: 05409427702 Unique Serial #: Product Information: USE HOS-0427702 Lot#: 41-407-DK-01 Oby: 25	250LD TO: Name: THOMAS G SERIO, MD Address: 1802 MICCOSUKEE COMMONS DR TALLAHASSEE FL 32308 Date Purchased & Ref: 01/14/16 01110644001	SHIPPED TO: Name: THOMAS G SERIO, MD Address: 1802 MICCOSUKEE COMMONS DR TALLAHASSEE FL 32308 Date Received & Ref: 01/14/16 01110644001
Supplier: INSOURCE:INCO AME	SOLD TO: Name: Address:	SHIPPED TO: Name: Address:
System, you	Date Purchased & Ref : SOLD TO; Name: Address:	Date Received & Ref : SHIPPED TO: Name: Address:
ckaging	Date Purchased & Ref : (TS) Transaction Statement: This Company complied w	Date Received & Ref : ith each applicable subsection of FDCA Sec. 581 (27) (A) – (G)
	(A) is authorized as required under the Drug Supply Chain Security Ad (B) received the product from a person that is authorized as required u (C) received transaction information and a transaction statement from t (D) did not knowlingly ship a suspect or liegitimate product; (E) had systems and processes in place to comply with verification req (F) did not knowlingly provide false transaction information; and (G) did not knowlingly after the transaction history.	nder the Drug Supply Chain Security Act; the prior owner of the product, as required under section 582;



Integration of FDA/Medispan Product Catalogs

Updated Fields for 2017
Optionally Can Be Added To Search
Filters

Field Name	Field Description
FDANAME	Name
FDASUFF	Suffix
FDAGENNAME	Generic Name
FDADOSAGE	FDA Dosage
FDAROUTE	Route
FDALABELER	Labeler
FDASUBSTANCE	FDA Substance
FDASTRENGTH	FDA Strength
FDASTRUNIT	FDA Strength Unit
FDAPHARM	FDA Pharm
FDASCHED	FDA Schedule
FDAPACK	FDA Package
FDAPRODUCTID	FDA Product ID

Field Name	Field Description
MSPAN.DOSAGE	MEDISPAN Dosage
MSPAN.MFG	MEDISPAN Mfg
MSPAN.IMPRINT	MEDISPAN Imprint
MSPAN.CATDESC	MEDISPAN Category Descriptions
MSPAN.DESCRDESC	MEDISPAN Standard Descriptions
MSPAN.BASICDESC	MEDISPAN Basic Descriptions
MSPAN.LTEXT	MEDISPAN Addl Text
DRUG.DOSAGE	Product Dosage Form
FDAPRODUCTID	Product id from FDA
FDAAPP	FDA Application number
MSPAN.GPI	GPI Number
MSPAN.SIZE	Medispan Size
MSPAN.STRENGTH	Medispan Strength
MSPAN.PILL.CNT	Medispan Pill Count
MSPAN.GENERIC.LIST	List of other generics (NDC)
MSPAN.BRAND	Brand Name
MSPAN.GENERIC	Generic Name
MSPAN.STORAGEINFO	Medispan Storage Info
MSPAN.GPPC	Medispan GPPC code
MSPAN.RXOTC	Medispan RX/OTC
MSPAN.DEACLASS	Medispan DEA Class
MSPAN.CONTROLLEDCLASS	Medispan Controlled Class



Integration of FDA/Medispan Product Catalogs

Updated Fields for 2017
Optionally Can Be Added To Search
Filters

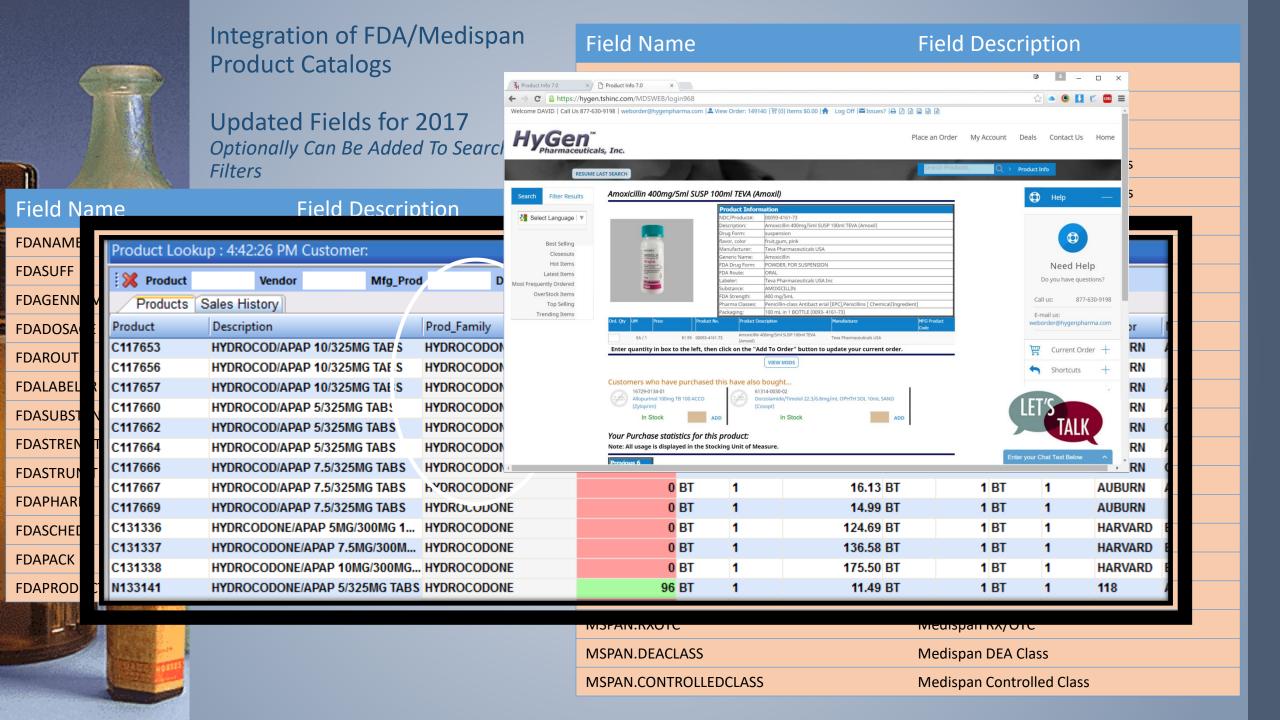
	Field Name	Field Description
	MSPAN.DOSAGE	MEDISPAN Dosage
	MSPAN.MFG	MEDISPAN Mfg
	MSPAN.IMPRINT	MEDISPAN Imprint
	MSPAN.CATDESC	MEDISPAN Category Descriptions
ı	MSPAN.DESCRDESC	MEDISPAN Standard Descriptions

Field Name

Field Description

FDANAME	Product Lookup : 4:42:26 PM Customer:														
FDASUFF	Product	Vendor	Mfg_Prod	Des	noito [*]	HYD Stock		NDC	Cus	t ;	⊘ Pric	e 🔔 🔾	0 0		
FDAGENN	Products	Sales History													
FDADOSA	Product	Description		Prod_Family		Available	StkUM	StkQTY	List	PrcUM	PrcQty	Sell Um	Sell Qty	Vendor	
FDAROUT	C117653	HYDROCOD/APAP 1	0/325MG TAB \$	HYDROCODONE			0 BT	1		10.90 BT		1 BT	1	AUBURN A	
	C117656	HYDROCOD/APAP 1	0/325MG TAE S	HYDROCODONE			0 BT	1		50.40 BT		1 BT	1	AUBURN	
FDALABEL	C117657	HYDROCOD/APAP 1	0/325MG TAE S	HYDROCODONE			0 BT	1		51.58 BT	,	1 BT	1	AUBURN A	
FDASUBST	C117660	HYDROCOD/APAP 5	/325MG TABS	HYDROCODONE			0 BT	1		13.80 BT		1 BT	1	AUBURN A	
	C117662	HYDROCOD/APAP 5	/325MG TABS	HYDROCODONE			0 BT	1		44.72 BT		1 BT	1	AUBURN (
FDASTREN	C117664	HYDROCOD/APAP 5	/325MG TABS	HYDROCODONE			0 BT	1		67.65 BT		1 BT	1	AUBURN A	
FDASTRUI	C117666	HYDROCOD/APAP 7	.5/325MG TABS	HYDROCODONE			0 BT	1		18.65 BT		1 BT	1	AUBURN (
	C117667	HYDROCOD/APAP 7	.5/325MG TABS	hydrocodone			0 BT	1		16.13 BT		1 BT	1	AUBURN A	
FDAPHAR	C117669	HYDROCOD/APAP 7	.5/325MG TABS	HYDROCODONE			0 BT	1		14.99 BT		1 BT	1	AUBURN	
FDASCHE	C131336	HYDRCODONE/APAF	P 5MG/300MG 1	HYDROCODONE			0 BT	1		124.69 BT		1 BT	1	HARVARD E	
FDAPACK	C131337	HYDROCODONE/APA	AP 7.5MG/300M	HYDROCODONE			0 BT	1		136.58 BT	,	1 BT	1	HARVARD E	
	C131338	HYDROCODONE/APA	AP 10MG/300MG	HYDROCODONE			0 BT	1		175.50 BT		1 BT	1	HARVARD E	
FDAPROD	N133141	HYDROCODONE/APA	AP 5/325MG TABS	HYDROCODONE			96 BT	1		11.49 BT		1 BT	1	118 A	





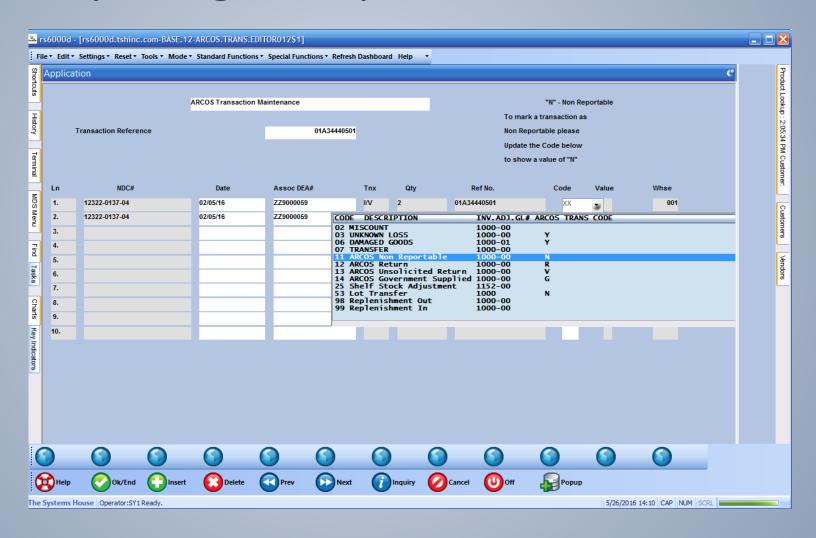


Arcos Reporting and Updates

- Added options for selection of Acquisition, Purchase, and Sales transactions to the ARCOS Transaction Report
- > Updated the ARCOS EOY format with the new requirements
- New report option based off the ARCOS, State Pharma Report. This would be used for OARRS.
- Added warehouse prompts to the DEA Inventory Report, DEA Receipts Posting Register and Lot Tracking Report
- ARCOS Transaction Maintenance gives the user the option to exclude transactions from being reported

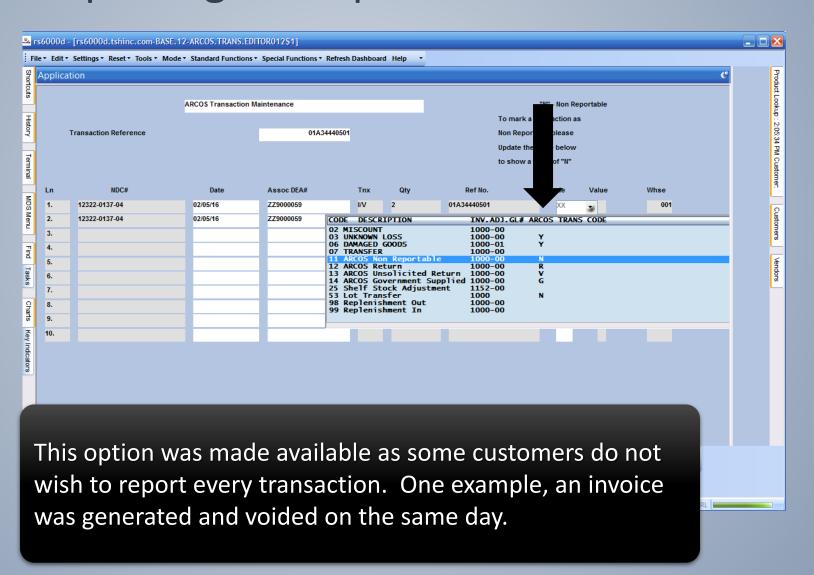


Arcos Reporting and Updates





Arcos Reporting and Updates





Pharma Enhancements Recap

- > HDMA EDI 856/E-Pedigree Track and Trace
- > Serialization and Traceability
- > Suspicious Order Monitoring System (Excessive Product Usage)
- > CSOS Options
- > Pedigree
- > Track and Trace Options
- > ARCOS and Reporting Updates

